GLYCINE - glycine irrigant
B. Braun Medical Inc.

DESCRIPTION

Each 100 mL contains:
Glycine USP.....1.5 g
Water for Injection USP ..... qs
pH: 6.1 (4.5–6.5)
Calculated Osmolarity: 200 mOsmol/liter
The formula of the active ingredient is:

Ingredient	Molecular Formula	Molecular Weight
Glycine USP	NH_2CH_2COOH	75.07

1.5% Glycine Irrigation USP is a sterile, nonpyrogenic aqueous solution suitable for urologic irrigation. This solution is slightly hypotonic.
The plastic container is a copolymer of ethylene and propylene formulated and developed for parenteral drugs. The copolymer contains no plasticizers and exhibits virtually no leachability. The plastic container is also virtually impermeable to vapor transmission and therefore, requires no overwrap to maintain the proper drug concentration. The safety of the plastic container has been confirmed by biological evaluation procedures. The material passes Class VI testing as specified in the U.S. Pharmacopeia for Biological Tests – Plastic Containers. These tests have shown that the container is nontoxic and biologically inert.

CLINICAL PHARMACOLOGY

1.5% Glycine Irrigation USP is nontoxic, nonhemolytic, not sticky, and has a refractive index close to that of water. These properties make it useful as a urologic irrigating fluid, particularly during transurethral surgical procedures where the irrigant may be absorbed through cut venous sinuses.
Systemically absorbed glycine is primarily metabolized by transamination to serine, and by deamination to ammonia which is normally removed by its conversion to urea. A portion of the absorbed glycine is excreted by the kidneys.

INDICATIONS AND USAGE

1.5% Glycine Irrigation USP is indicated as an irrigant during transurethral prostatic or bladder surgery.

CONTRAINDICATIONS

1.5% Glycine Irrigation USP is not for injection. It is contraindicated in patients with anuria.

WARNINGS

Solutions for urologic irrigation must be used with caution in patients with severe cardiopulmonary or renal dysfunction.
The amount of fluid absorbed during a transurethral resection is a function of the volume and hydrostatic pressure of the irrigant used, the number and size of venous sinuses opened, and the duration of the procedure. Since irrigating fluids used during transurethral prostatectomy have been demonstrated to enter the systemic circulation in relatively large volumes, any irrigation solution must be regarded as a systemic drug.
Absorption of large amounts of fluids containing glycine and the resultant osmotic diuresis may significantly affect cardiopulmonary and renal dynamics. Absorption of large amounts of irrigating solution can also result in pronounced hyponatremia and water intoxication.
After opening container, the contents should be used promptly to minimize the possibility of bacterial growth or pyrogen formation. Discard unused portion of irrigating solution since it contains no preservative.

PRECAUTIONS

Cardiovascular status, especially in patients with cardiac disease, should be carefully determined before and during transurethral resection of the prostate when using 1.5% Glycine Irrigation USP as an irrigant. The fluid absorbed into the systemic circulation via severed prostatic veins may produce significant extracellular fluid expansion and lead to fulminating congestive heart failure.
Shift of sodium-free intracellular fluid into the extracellular compartment following systemic absorption of 1.5% Glycine Irrigation USP may lower serum sodium concentration and aggravate pre-existing hyponatremia.
Excessive loss of water and electrolytes may lead to serious imbalances. Sustained diuresis from transurethral irrigation with 1.5% Glycine Irrigation USP may obscure and intensify inadequate hydration or hypovolemia.
Care should be exercised if impaired liver function is known or suspected. Under such conditions, ammonia resulting from the metabolism of glycine may accumulate in the blood.
Use only if solution is clear and container and seal are intact.

ADVERSE REACTIONS

Adverse reactions may include fluid and electrolyte disorders such as acidosis, electrolyte loss, marked diuresis, urinary retention, edema and dehydration; cardiovascular/pulmonary disorders such as pulmonary congestion, hypotension, tachycardia, angina-like pain and thrombophlebitis; other possible reactions include visual disturbances, convulsions, nausea, vomiting, diarrhea, vertigo and urticaria.

Literature includes reports on hyponatremia, hyperammonemia, transient blindness, coma (immediate or delayed), and digitalis toxicity in digitalized patients.

If an adverse reaction occurs, discontinue the irrigant and reevaluate the clinical status of the patient.

DOSAGE AND ADMINISTRATION

As required for irrigation.

1.5% Glycine Irrigation USP should be administered only by the appropriate transurethraI urologic instrumentation.

It has been reported that absorption is significantly increased if the container is higher than 60 cm (24") above the patient.

This drug product should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

1.5% Glycine Irrigation USP is supplied sterile and nonpyrogenic in plastic irrigating containers. The 2000 mL containers are packaged 8 per case and the 4000 mL containers are packaged 4 per case.

NDC	Cat. No.	Size
1.5% Glycine Irrigation USP (Canada DIN 01963945)		
0264-2302-50	R6415-01	2000 mL
0264-2302-70	R6417	4000 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product. Do not warm above 150°F (66°C).

Rx only

Revised: January 2003

Directions for Use

Aseptic technique is required.

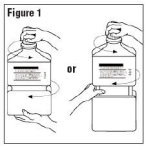
1. Caution – Before use, perform the following checks:
   (a) Read the label. Ensure solution is the one ordered and is within the expiration date.
   (b) Invert container and inspect the solution in good light for cloudiness, haze, or particulate matter; check the container for leakage or damage. Any container which is suspect should not be used.

Use only if solution is clear and container and seal are intact.

Single dose container.

Not for injection.

2. Outer Closure Removal – Grasp the container with one hand and turn the breakaway ring counterclockwise with the other hand until slight resistance is felt. Then, twisting the container in the opposite direction, turn the breakaway ring **sharply** until the entire outer cap is loose and can be lifted off.



3. Connect the administration set through the sterile port according to set instructions or remove screw cap and pour.

4. Do not warm above 150°F to assure minimal bottle distortion. Keep bottles upright.

Notice: An additional suspension device has been added to the container hanger tab on the 4000 mL container. Please use this device to suspend the container to permit twisting without the potential for breakage of the integral hanger.

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